IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

CIVIL ACTION No. 4:21-cv-10312

Hon. F. Kay Behm

PLAINTIFF'S MOTION TO EXCLUDE TESTIMONY OF MANSOOR M. AMIJI, PH.D.

Stanley H. Kremen
Attorney at Law
4 Lenape Lane
East Brunswick, NJ 08816
(732) 593-7294
shk@shk-dplc.com
Attorney for the Plaintiff

Keith Altman
The Law Office of Keith Altman
38228 West 12 Mile Road, Suite 375
Farmington Hills, Michigan 48334
(248) 987-8929
keithaltman@kaltmanlaw.com
Attorney for the Plaintiff

TABLE OF CONTENTS

LIST OF EXHIBITS

TABLE OF AUTHORITIES

CASES

Pages

STATUTES AND RULES

I. RELIEF REQUESTED

Comes now the Plaintiff, by and through his attorneys, requesting that the court exclude the Defendant from calling Dr. Mansoor M. Amiji to testify regarding patent invalidity at trial.

II. ISSUES

Defendant intends to call Dr. Mansoor M. Amiji as an "expert" witness to testify regarding validity of U.S. Patent No. 8,163.802 ("the '802 Patent"), *i.e.*, the patent in suit. Dr. Amiji should not be allowed to give his opinions because:

1. Since he is not an attorney or a legal expert, or a patent agent licensed by the United States Patent and Trademark Office ("USPTO") to practice therein in matters regarding patents, he cannot give a legal opinion as to whether the claims of a patent are valid under the various patent statutes.

2. All of the opinions that Dr. Amiji rendered in his opening expert report[1] are legal opinions. which purport to establish invalidity of the claims of the '802 Patent that are at issue in this case. As such, he is not qualified to testify as to his opinions on invalidity of said claims.

[1] "Opening Expert Report of Mansoor M. Amiji, Ph.D. on Invalidity," dated June 27, 2022. Already filed as ECF 56-2 as an exhibit to Defendant's Motion.

3. Despite rendering only legal opinions to support his allegations of invalidity, Dr. Amiji's report and deposition testimony[2] demonstrate a fundamental unfamiliarity with patent law and the methodology used to invalidate patent claims. As such, Dr. Amiji is not qualified to testify as to his opinions on invalidity of the claims of the '802 Patent.

4. Dr. Amiji's opinions as a whole do not meet the reliability requirements of admissibility under Fed. R. Evid 702 and 703 as set forth in *Daubert v. Merrill Pharmaceuticals, Inc.*, 509 U.S. 579, 580 (1993) and *Kuhmo Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999).

5. Dr. Amiji's legal opinions are routinely excluded in whole or in part to show patent invalidity in patent infringement trials.

III. BACKGROUND INFORMATION

Dr. Amiji presented himself as an expert in "pharmaceutical sciences and drug formulation development and characterization." He specializes in "drug formulation development and targeted delivery of therapeutics." (ECF 56-2, pg 2, ¶8.)[3] He is a pharmacist registered to practice in Massachusetts. He is also a professor of pharmaceutical sciences and jointly a professor of chemical engineering as well as an affiliate faculty member in biomedical

[2] Dr. Amiji's Deposition Testimony taken on October 14, 2022 is concurrently submitted herewith. Some text on pages 78-79 was redacted at defense counsel's request.

[3] Hereinafter, page numbers in ECF 56-2 will refer to Dr. Amiji's original page numbers. Thus, the original Page 1 in the report begins on Page 6 of the ECF PDF file.

engineering, all these positions being held at Northeastern University in Boston. *Id.* Dr. Amiji received his Ph.D. from Purdue University in 1992. While at Purdue, he took "several pharmaceutics courses and had hands-on training in pharmaceutical formulation development and characterization." *Id.* His qualifications as an expert in pharmaceutical science are not in question. However, Plaintiff challenges his qualifications to render the opinions on patent invalidity that were stated in his reports.

In his opening report (ECF 56-2), Dr. Amiji rendered the following opinions:

1. "[T]he characteristics of a person of ordinary skill in the art of the ’802 Patent would be someone who had at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation. Also, a person of ordinary skill in the art may have worked as part of a multidisciplinary team— including a chemical engineer, microbiologist, or polymer chemist—and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, e.g., to solve a given problem." (ECF 56-2, pg. 28, ¶68.)

2. "Claims 1, 2, 6, and 7[4] are invalid for being directed to ineligible subject matter under 35 U.S.C. § 101." (ECF 56-2, pg. 95, § XII.)
3. "Claims 1, 2, 6, and 7 are invalid under 35 U.S.C. §§ 101/112 for lack of credible utility." (ECF 56-2, pg. 99, ¶212.)
4. "Claims 1, 2, 6, and 7 are invalid for lack of enablement." (ECF 56-2, pg. 101, § XIV.)
5. "Claims 1, 2, 6, and 7 are invalid for lack of adequate written description." (ECF 56-2, pg. 108, § XV.)
6. "Claims 1, 2, 6, and 7 are invalid in view of Wadstrom[5] alone or in combination with Rolf[6]. " (ECF 56-2, pg. 44, § IX.)
7. "Claims 1, 2, 6, and 7 are invalid in view of Wahi '488[7] alone, or in combination with Rolf." (ECF 56-2. pg. 58, § X.)
8. "Claims 1, 2, 6, and 7 are invalid in view of Baker '189[8] or Baker '476[9] alone, or in combination with Rolf or Khaled[10] or Rabe[11] or Katz[12] or Wahi '790[13]." (ECF 56-2, pg. 74, § XI.)

---

[4] Claims 1, 2, 6, and 7 of the '802 Patent are the claims at issue in this present lawsuit.
[5] U.S. Pat. Appl. Pub. No. 2006/0163149 A1, USPTO publication date: July 27, 2006.
[6] U.S. Pat. Appl. Pub. No. 2001/0071757 A1, USPTO publication date Nov. 20, 2001.
[7] U.S. Patent No. 5,468,488 issued on Nov. 20, 1995.
[8] U.S. Patent No. 9,559,189 issued on May 6, 2003.
[9] U.S. Pat. Appl. Pub. No. 2009/0143476 A1, USPTO publication date June 4, 2009.
[10] U.S. Pat. Appl. Pub. No. 2001/0243237 A1, USPTO publication date Oct. 18, 2007.
[11] U.S. Patent No. 6,531,142 issued on Mar. 11, 2003.
[12] U.S. Pat. Appl. Pub. No. 2002/0006961 A1, USPTO publication date Jan. 17, 2002.
[13] U.S. Pat. Appl. Pub. No. 2003/0161790 A1, USPTO publication date Aug. 28, 2003.

All of Dr. Amiji's opinions cited *supra* recite legal issues. Dr. Amiji keeps emphasizing that he is not an attorney. (ECF 56-2, pg. 13, ¶30; *See also* Depo. Amiji, 18:21-22.) He discusses his lack of relevant legal training regarding determination of patent validity in his deposition (Depo Amiji, pp. 18 - 19). He never attended law school. (*Id.* at 18:23-24.) He never sat for a bar examination in any state. (*Id.* at 19:1-2.) He is not licensed to practice in patent matters by the USPTO. (*Id.* at 19:4-7.) He has never read the USPTO Manual of Patent Examining Procedure ("MPEP"), and he never heard of it. (*Id.* at 19:8-15.) The MPEP is a USPTO publication that establishes the legal standards and procedures to be followed by USPTO patent examiners for allowing patent applications to issue as patents or to reject claims during their prosecution.

In his opening report (ECF 56-2, pg. 13, ¶30), Dr Amiji says, "I am not an attorney. For purposes of this report, I have been informed about certain aspects of the law that are relevant to my opinions, as described below." When asked who informed him, he answered, "counsel." (*e.g.,* Depo. Amiji 19:24; 20:3-6; 51:12-15.)

In an unrelated lawsuit[14] alleging infringement of the '802 Patent by other defendants, counsel for those other defendants engaged Dr. Amiji to provide an expert declaration[15]. The defendants in that matter were represented by different counsel than those in the present lawsuit. Dr. Amiji's declaration alleged that the claims of the '802 Patent at issue in this present lawsuit are obvious over Wadstrom alone or in view of Rolf and Wahi '488 alone or in view of Rolf. The obviousness arguments presented by Dr. Amiji in his declaration in that matter regarding Wadstrom, Rolf, and Wahi '488 are virtually identical to those expressed in Dr. Amiji's opening report (ECF 56-2). That previous lawsuit settled before Dr. Amiji's declaration could be considered.

At his deposition of October 14, 2022, Dr. Amiji testified that counsel in the prior lawsuit provided the patent references to him (*i.e.,* Wadstrom, Rolf, and Wahi '488), and Defendant's Counsel in the present lawsuit provided him with the remaining prior art patent references. (Depo. Amiji, 60:8 - 63:10.) Dr. Amiji testified that he did not recall searching for the patent documents himself. (*Id.* 61:14-19; 62:13-14; and 63:1-5.) Thus, Dr. Amiji's task in both cases was to use the prior art documents provided to him

[14] *Trutek Corp. v. Matrixx Initiatives, Inc.*, DNJ Civil Action No. 3:19-cv-17647-BRM-ZNQ-PHV.

[15] USPTO Patent Trial and Appeal Board (PTAB) *Inter Partes* Review Case No. IPR2020-01592.

to affirm counsel's allegations of invalidity for the claims at issue of the '802 Patent.

Because Dr. Amiji's analysis of validity of the claims at issue of the '802 Patent were primarily legal, Plaintiff had no alternative but to engage a rebuttal expert who was both an expert on patent law as well as on the technical aspects of the '802 Patent. The '802 Patent is presumed valid. 35 U.S.C. § 282(a). *Structural Rubber Prods. Co. v. Park Rubber Co.,* 749 F.2d 707, 741 (Fed. Cir. 1984). While the patented technology is involved, the determination of patent invalidity is legal in nature, and must be demonstrated by the Defendant by clear and convincing evidence. *Microsoft Corp. v. i4i Limited Partnership,* 564 U.S. 91 (2011). Amirali Y. Haidri is a patent attorney who received a bachelor's degree in chemical engineering and a masters degree in organic chemistry. Mr. Haidri began working as a patent attorney in 1981. He is intimately familiar with the technology of the '802 Patent since he represented Plaintiff in its patent infringement lawsuit against Matrixx Initiatives, Inc. (See Note 14.) Based on his background in chemistry and chemical engineering, he is able to opine on the legal and technological aspects of the '802 Patent. Mr. Haidri's expert rebuttal report

on invalidity was presented to the Court by Defendant as ECF 56-3. Mr. Haidri's resume is attached to ECF 56-3 as Exhibit A[16].

Each of the opinions in Mr. Haidri's report was presented in rebuttal to the corresponding opinion of Dr. Amiji. Virtually all of Dr. Amiji's opinions were legal in nature, but where Dr. Amiji cited technology, Mr. Haidri countered with a technological opinion.

IV. LEGAL AUTHORITY

Fed. R. Evid. 702 sets forth the evidentiary standard for admitting testimony of experts at trial.

(a) While Dr. Amiji's expertise in pharmaceutical science is not in question, his specialized knowledge does not support the opinions expressed in his reports regarding invalidity, and the opinions expressed by him will not help the trier of fact to understand the evidence or to determine a fact at issue.

(b) The opinions expressed by Dr. Amiji in his reports regarding invalidity are not based on sufficient facts or data, and are contrary to existing law.

(c) The opinions expressed by Dr. Amiji in his reports regarding invalidity are not the product of reliable principles and methods.

[16] Mr. Haidri's resume is Exhibit A to ECF 56-3 on Pages 90-94 of the ECF PDF file.

(d) Dr. Amiji has not reliably applied the appropriate principles and methods to the facts of the case.

It is not the purpose of this motion to argue that the claims at issue of the '802 Patent are valid. They are presumed valid, and it is the Defendant's burden to prove invalidity by clear and convincing evidence. *Microsoft v. i4i.* Instead, this motion argues that Dr. Amiji is not qualified to render his invalidity opinions and that if rendered would be unreliable and confusing to a jury.

Dr. Amiji's opinions regarding invalidity of the claims at issue in the '802 Patent have been listed *supra*. All of the opinions in Dr. Amiji's opening report (ECF 56-2) are legal in nature. Although defendant's counsel may have informed him of the various legal issues regarding invalidity, Dr. Amiji displayed a fundamental misunderstanding of those issues.

1. THE PERSON HAVING ORDINARY SKILL IN THE ART

Claim terms "are generally given their ordinary and customary meaning as understood by a **person of ordinary skill in the art**.[17]" *Thorner v. Sony Comp. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)

Patent law statutes 35 U.S.C. §§ 112 and 103 regarding enablement and obviousness involve the judgment of a person having ordinary skill in

[17] Emphasis added.

the art (often abbreviated as "PHOSITA"). A PHOSITA is a legal fictional individual who is merely a technician, but who also has an awareness of all the prior art in his or her field. However, he or she is not an automaton, and is capable of some innovation. The enablement requirement of 35 U.S.C. §112 in part requires that, "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable **any person skilled in the art**[18] to which it pertains, or with which it is most nearly connected, to make and use the same,"

35 U.S.C. § 103 provides in part that, "[a] patent for a claimed invention may not be obtained **...** if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to **a person having ordinary skill in the art**[19] to which the claimed invention pertains."

Thus, a precise definition of the qualifications of a PHOSITA in the particular field of the invention is required for a proper evaluation of the enablement requirement of 35 U.S.C § 112 and a proper determination of obviousness under 35 U.S.C. § 103. Attributing wrong qualifications to a

[18] Emphasis added.
[19] Emphasis added.

proposed PHOSITA at trial would result in the trier of fact examining enablement and obviousness through an improper lens. Incorrect determination of the qualifications of a PHOSITA has resulted in reversible error. *Custom Accessories, Inc. v. Jeffrey-Allen Indus., Inc.,* 807 F.2d 955 (Fed. Cir. 1986).

Dr. Amiji opined that a PHOSITA must have attained "at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation." (ECF 56-2, pg. 28, ¶68.) However, this Court disagreed with Dr. Amiji, and adopted Plaintiff's definition of a PHOSITA. (ECF 53, pp. 2 and 10. See also Court's discussion *Id.,* at pp. 8-10.) The definition put forth by Plaintiff is:

> *The person of ordinary skill would not have read the '802 Patent stand-alone. Based on his knowledge and experience, this person would be familiar with all the ingredients listed in the ten formulations shown in the '802 Patent. He would have the skill and experience to duplicate those formulations once having seen their list of ingredients. He must know enough chemistry and biology to be familiar with cationic agents and biocidic agents. He must have knowledge of the various airborne "harmful particles," such as bacteria, viruses, pollen, and other allergens. He must know enough undergraduate physics to understand electrostatic fields as well as the principles of electrostatic attraction and repulsion, adhesion, and cohesion. to that end, he needs familiarity with ingredients that are surfactants, thickeners, and binders.*
> (ECF 40, pg. 12.)

In his deposition, Dr. Amiji testified that he considers himself to be a PHOSITA. (Depo. Amiji, 81:22 - 82:8.) However, Dr. Amiji is a person having extraordinary skill in the art. By viewing the issues of claim construction, enablement, and obviousness through the lens of an incorrect PHOSITA, and imagining himself as that PHOSITA, his opinions were viewed improperly through his own lens.

2. DR. AMIJI'S OPINIONS REGARDING 35 U.S.C. § 101

35 U.S.C. § 101 states, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

a. SUBJECT MATTER ELIGIBILITY

In Dr. Amiji's first opinion regarding this statute, he stated that the claims at issue "are invalid for being directed to ineligible subject mater under 35 U.S.C. § 101." (ECF 56-2, pg. 95, § XII.) Here, Dr. Amiji misinterpreted the statute and law regarding subject matter eligibility. First, he ignored the first basic inquiry for subject matter eligibility where claim 1 is directed to a method (*i.e.,* a process), and claims 2, 6, and 7 are directed to a formulation (*i.e.,* a composition of matter). Instead, he only addressed the second inquiry to determine whether the invention's claims wholly embrace

non-man-made judicial exceptions to patentability, *e.g.,* laws of nature, physical phenomena, and abstract ideas, or conversely whether "it is a particular practical application of a judicial exception." *Diamond v. Chakrabarty,* 447 U.S. 303, 309 (1980). *See also* MPEP § 2106(II).

Dr. Amiji discussed the law regarding these judicial exceptions to patentability, but he ignored whether the claims at issue represent "a particular practical application of a judicial exception. (ECF 56-2, pp. 18-19, ¶¶ 42-43.) Then, under a heading of Subject Matter Eligibility, he states his opinion as, "XII. Analysis: Claims 1, 2, 6, and 7 are invalid for being directed to ineligible subject matter under 35 U.S.C. § 101." (*Id.* pg. 95.) He states:

> *The '802 Patent is directed to the effects of a law of nature or a natural phenomena, namely the principle that like charges repel each other, while unlike charges attract, e.g., a positive charge attracts a negative charge. While the Challenged Claims of the '802 patent recite additional elements, each of those additional claim elements are either conventional steps that are well known to a POSA[20] or depend on the very same law of nature or natural phenomena. Thus, in my opinion, the '802 Patent claims do not recite any inventive concept that would transform the law of nature into a patent eligible invention.*
> (*Id.* at ¶ 202.)

[20] POSA (**P**erson of **O**rdinary **S**kill in the **A**rt) is Dr. Amiji's acronym instead of the more common acronym PHOSITA (**P**erson **H**aving **O**rdinary **S**kill **I**n **T**he **A**rt).

Pages 31 through 46 of Dr. Amiji's deposition taken on October 14, 2022 deal with Dr. Amiji's understanding of subject matter eligibility under 35 U.S.C. § 101.

In his deposition, Dr. Amiji was asked, "You express an opinion about the statute of 35 USC 101, what is 101?" (Depo. Amiji, 31:22.) Defense Counsel objected to the question stating that he is not a legal expert. (*Id* at 32:9-14.)

When pressed further, Dr. Amiji stated, "**...** my understanding of the patent law is what was provided to me. and then subsequent to that, I have discussed the various parts of those standards." (*Id.* at 33:14-20.) Regarding the first inquiry under 35 U.S.C. § 101, Dr. Amiji admitted, after repeated questioning, that claim 1 recites a process and that claim 2 recites a composition of matter. However, he still maintained that the claims contained ineligible subject matter (*viz.,* electrostatic attraction) and that he made that determination through the lens of a PHOSITA. He said, "**...** I'm not a lawyer, but as I read the claims, and in view of a personal [*sic.*] skill in the art,[21] **...** " (*Id.* 35:6-7) He further said, "[m]y understanding is that for subject mater to be patentable, there has to be some novelty beyond what is

[21] The Deponent actually said, "person of skill in the art."

well known to personal [*sic.*] skill in the art as occurring by nature." (*Id.* at 38:9-12.) This is not the proper standard of review.

First, a PHOSITA is never mentioned in the Statute. 35 U.S.C. § 101 requires an objective determination. Dr. Amiji applied the facts to an incorrect interpretation of the statute.

In the first inquiry of §101, if a claim falls objectively into one of the four stated categories, the subject matter is eligible for patentability. Dr. Amiji ignored this first inquiry. Instead he concentrated on the second inquiry, which arises from the objective fact that one cannot patent a non-man made discovery such as a law of nature, a physical phenomenon, or an abstract idea.

However, all inventions utilize laws of nature in some way. While Albert Einstein could not patent his famous law equating mass and energy, $E=mc^2$, an inventor may patent a nuclear reactor that uses that law. None of the claims at issue in the '802 patent claim electrostatic attraction. However, the claims all utilize this law of nature. The claimed formulations (*i.e.,* claims 2, 6, and 7) contain a cationic agent[22] as but one of its ingredients. And, process claim 1 recites "electrostatically attracting" as but one of its steps. From Dr. Amiji's testimony, it is difficult to ascertain whether he

[22] A cationic agent is an ingredient that exhibits a positive electrostatic charge.

realizes that an invention may utilize a law of nature in one or more of its elements and still be patentable. In his report, Dr. Amiji states:

> *While the Challenged Claims of the '802 patent recite additional elements, each of those additional claim elements are either conventional steps that are well known to a POSA, or depend on the very same law of nature or natural phenomena.* (ECF 56-2, pg. 95, ¶202.)

Other than the fact that the claims recite additional elements, the above statement is untrue. However, the issue here is that this viewpoint is not the proper standard for a §101 inquiry into subject matter eligibility.

Subject matter eligibility under 35 U.S.C. § 101 is a legal issue, and while defense counsel may have informed Dr. Amiji of certain standards, it is clear that (1) he does not know the meaning of the statute regarding subject matter eligibility; (2) he used the wrong standards to determine whether the claims contain eligible subject matter; and (3) he is not qualified as an expert to testify on these matters.

b. CREDIBLE UTILITY

In his report, Dr. Amiji opined that the claims at issue "are invalid under 35 U.S.C. §§ 101/112 for lack of credible utility." (ECF 56-2, pg. 99, ¶212.) 35 U.S.C. §101 requires that a patentable invention be new and useful. Credible utility is a definite requirement of 35 U.S.C. § 101. If an

invention is not useful, no patent may issue. However, there is no such requirement usefulness within any of the six provisions of 35 U.S.C. § 112.

The specification of the '802 Patent discloses ten different formulation embodiments in which the ingredients are listed in percent ranges by weight. According to the inventor, all of the formulation embodiments function effectively as described in the disclosure. However, in Dr. Amiji's report, he states that unless data or test results are provided in the specification, a PHOSITA would be unable to determine whether the formulations listed would work as described. (ECF 56-2, pp. 99-100, ¶214.)

While inclusion of test data and testing protocols are sometimes provided in patent specifications, this is not a requirement either under 35 U.S.C. § 101 or § 112. As argued *supra*, 35 U.S.C. § 101 makes no mention of a PHOSITA. Further, 35 U.S.C. § 112 makes no mention of credible utility. Dr. Amiji is confusing this with the enablement requirement of §112(a) or pre-AIA § 112, first paragraph. That enablement requirement will be addressed *infra*.

At his deposition, Dr. Amiji was asked whether a formulation that actually inhibits infection due to inhalation of harmful particles is useful. In response, he said that, "the teaching of the 802 would be useful, but it's not." (Depo. Amiji, 47:13.) When questioned whether it is true "that no statute or

rule specifically required such data or test results for patentability," he responded, "[m]y opinion is that the 802 patent doesn't teach to a personal [*sic.*] skill in the art specific composition that enables the claim." (*Id.* at 47:21 - 48:4.)

It should be clear at this point that Dr. Amiji presented opinions of a legal nature regarding 35 U.S.C. § 101, and that he misinterpreted the requirements of the statute. Effectively, Dr. Amiji created his own criteria of determining subject matter patent eligibility and credible utility that do not comport with existing law. His opinions are "made up." "Nothing in either *Daubert*[23] or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *General Elec. Co. v. Joiner*, 522 U.S. 136, 137 (1997).

3. DR. AMIJI'S OPINIONS REGARDING 35 U.S.C. § 112

The first paragraph of pre-AIA[24] 35 U.S.C. § 112 reads as follows:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

[23] *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

[24] "AIA" is an acronym for the America Invents Act, enacted into law by the 112th Congress on September 16, 2011.

Currently, 35 U.S.C. § 112(a) reads as follows:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.*

Because the '802 Patent is based upon a patent application filed in 2009, and the patent issued in 2012, there is some debate as to which statute should apply. However, the §112 paragraphs above apply equally when evaluating the '802 Patent. As can be observed, § 112(a) or pre-AIA § 112, first paragraph has three requirements:

- to provide a written description of the invention (*i.e.*, the **Written Description** requirement);
- "to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same" (*i.e.,* the **Enablement** requirement); and
- shall set forth the best mode contemplated by the inventor of carrying out his invention (*i.e.,* the **Best Mode** requirement).

Dr. Amiji's reports did not discuss the Best Mode requirement. Thus, we must look only at his analysis of the Written Description and Enablement requirements.

a. THE WRITTEN DESCRIPTION REQUIREMENT

In his opening report, Dr. Amiji stated that "claims 1, 2, 6, and 7 are invalid for lack of adequate written description." (ECF 56-2, pg. 108 § XV.) He states, "It is my opinion that the ’802 patent specification does not reasonably convey to a person skilled in the art that the inventor was in possession of any formulation or composition that would operate in the manner claimed in the ’802 patent as of the filing date of the application." (*Id.* at ¶236.)

To support this opinion, Dr. Amiji admits that the "specification provides numerous formulations and ranges of components," but he objects to the lack of test data that would show that these formulations would work as described. However, this is not the established standard. **Evidence of testing is not required**. It is merely required that the inventor provide a disclosure of his invention. Dr. Amiji misinterprets the written description requirement of 35 U.S.C. § 112.

In the specification of the '802 Patent, the inventor, Ashok Wahi, provided ten separate embodiments showing formulations that would function as described along with an explanation of the mechanism of operation. The composition of ingredients in the formulations is provided in ranges given in percent by weight. That means that for each disclosed

embodiment, many formulations exist, which satisfy the criteria of an adequate written description. More will be explained when discussing Dr. Amiji's opinions for the enablement requirement of 35 U.S.C. § 112, It is expected that a PHOSITA who is interested in making and using the invention would need to perform some experimentation, as long as such experimentation is not undue. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.,* 713 F.2d 788 (Fed. Cir. 1985).

Finally, Dr. Amiji said, "Nor is there any explanation or disclosure within the ’802 Patent that would demonstrate to a person skilled in the art that the mere fact of electrostatically inhibiting such particulate matter will be sufficient to render such particulate matter harmless." Once again, Dr. Amiji mistakes the written description requirement of § 112 for the enablement requirement.

b. THE ENABLEMENT REQUIREMENT

Dr. Amiji states his opinion that, "claims 1, 2, 6, and 7 are invalid for lack of enablement." (ECF 56-2, pg. 101, § XIV.) Dr. Amiji states:

> *The ’802 Patent also describes prior art patents addressing electrostatically charged compositions, but noting that “those compositions simply create an electrostatic field that helps to filter out oppositely charged materials” and that “[w]hile this action may offer suitable protection against particles that are inhaled passively, they suffer from the fact that they cannot completely deal with particulates that have their own internal means of overcoming the electrostatic forces, such as*

> *microorganisms that are motile within the air stream." '802 Patent at 2:42-52.*
> (ECF 56-2, pg. 102, ¶220.)

This section must be dealt with in two parts. First, in the patent application[25] that resulted in issuance of the '802 Patent, the preamble of claim 1 originally read:

> *A method for **electrostatically preventing harmful particulate matter from infecting an individual** through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:*

And, the preamble of claim 2 originally read:

> *A formulation for **electrostatically preventing harmful particulate matter from infecting an individual** through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:*

In the '802 Patent, the only difference is that the word "preventing" in the claims is replaced by the word "inhibiting."

On August 25, 2011, during prosecution of the patent application, the USPTO patent examiner issued an office action, which is submitted concurrently as Exhibit A. In that office action, the examiner rejected all pending claims under 35 U.S.C. § 112, first paragraph for failing to meet the

[25] U.S. Patent Application No. 12/467,271 filed by Ashok Wahi on May 16, 2009.

enablement requirement. (Exhibit A, pg. 2.) This was the only rejection made by the examiner. The examiner asserted that the term "preventing" means that "not even one of the infectious material is allowed to infect, *i.e.*, pass into the system of the host." (*Id.* at pg. 3.) The examiner held:

> *In order to overcome the rejection set forth infra, it is suggested that Applicant consider amending claims 1,2 and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting". While the latter is not specifically set forth in the present specification, it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole, i.e., no new matter would be introduced by the introduction of the term "inhibition" in the claims.* (*Id.* at pg. 2.)

In response, the Applicant amended the claims by changing the word "preventing" to the word "inhibiting." The claims of the '802 Patent are now bound to this amended interpretation by prosecution history estoppel. Thus, claims 1 and 2 of the '802 Patent allow for some infectious material to pass into the user's respiratory system.

In his deposition, when questioned about the above paragraph, Dr. Amiji said, "I understand what the examiner meant. I don't agree with the examiner, but I understand what he means." (Depo. Amiji 128:15.) It must be noted that the examiner is in a position of authority, and that this matter was considered by the USPTO prior to allowing the application to issue as the '802 Patent.

The second issue to be considered is the 35 U.S.C. § 112 requirement, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, **...**" Once again, Dr. Amiji objects to the lack of test data to demonstrate that the formulations in the various formulations contained in the ten listed embodiments actually work as described. As argued *supra*, this is not a requirement of any provision in patent law.[26] As long as a PHOSITA is able to make and use the invention without undue experimentation, the enablement requirement of 35 U.S.C. § 112 is satisfied. A patent is not required to be a manufacturing specification. Some experimentation is allowed, but it must not be undue. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.,* 713 F.2d. See also, *Engel Indus., Inc. v. Lockformer Co.,* 946 F.2d 1528 (Fed. Cir. 1991). Efficacy testing may be performed by the PHOSITA once the formulation is duplicated.

[26] Patents are regularly issued by the USPTO where there has been no actual reduction to practice, but rather where there has been a constructive reduction to practice. For example, a patent for a machine may be issued even if the machine had not been built prior to the application filing date.

In his report, Dr. Amiji said, "nor does the ’802 Patent provide any examples or any guidance as to how the percentages of components can be varied while still achieving 'the same results.'"

At the Markman Hearing held by this Court on November 15, 2022, much ado was made by Defendant that the ten formulation embodiments were disclosed in ranges and that there was no disclosure of a specific composition that enables the claim, and that it would take undue experimentation to develop such a specific composition. In response, Plaintiff stated that all the formulations would be effective as long as the ingredient concentrations remained within the stated ranges. Plaintiff pointed to the tenth embodiment as an example, and displayed a formula where most of the ingredient concentrations were in the midrange of those disclosed in the tenth embodiment. This formulation is shown in ECF 51-1, pg. 20. That formulation approximates the product first marketed by Plaintiff after the '802 Patent issued. Any pharmaceutical formulator who is a PHOSITA would know how to prepare this formulation using only the patent's specification as a guide.

At this point, it should be apparent that Dr. Amiji does not fully understand the written description requirement or the enablement requirements of 35 U.S.C. § 112.

4. DR. AMIJI'S OPINIONS REGARDING 35 U.S.C. § 102 AND § 103.

35 U.S.C. §§ 102, 103 deal with unpatentability of a claimed invention based upon prior art. 35 U.S.C. § 102(a)(1) states that, "a person shall be entitled to a patent unless **...** the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention **...**" 35 U.S.C. § 102(a)(1) is known as the ***anticipation statute***. A claim is anticipated, and therefore unpatentable, if **a single reference teaches every limitation of that claim**. *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631 (Fed. Cir. 1987). Unless every limitation of the claim is taught by a single prior art reference, the claim is not anticipated under § 102. Further, a prior art reference that is not enabled cannot be used to anticipate a claim. *Azko N.V. v. United States ITC*, 808 F.2d 1471 (Fed. Cir. 1986).

35 U.S.C. § 103 provides that even if a claimed invention is not identically disclosed as set forth in § 102, it would still be unpatentable if it is obvious to a PHOSITA. A PHOSITA is a fictitious person technically proficient in his art and who is familiar with all the prior art in his field. Although such a person is not an innovator, he is not an automaton either. However, he should be able to **combine a plurality of prior art references**

to teach every limitation of the claim. However, unless every limitation of the claim is taught by the prior art, the claim is not obvious under § 103.[27]

In his report, Dr. Amiji provided three opinions alleging invalidity of the claims of the '802 Patent based upon prior art:

- Claims 1, 2, 6, and 7 are invalid in view of Wadstrom[5] alone or in combination with Rolf[6]. (ECF 56-2, pg. 44.)
- Claims 1, 2, 6, and 7 are invalid in view of Wahi '488[7] alone, or in combination with Rolf. (ECF 56-2. pg. 58.)
- Claims 1, 2, 6, and 7 are invalid in view of Baker '189[8] or Baker '476[9] alone, or in combination with Rolf or Khaled[10] or Rabe[11] or Katz[12] or Wahi '790[13]. (ECF 56-2, pg. 74.)

The particulars of Plaintiff's rebuttal arguments to Dr. Amiji's opinions are contained in Amirali Haidri's reply expert report (ECF 56-3). Mr. Haidri has the educational requirements sufficient to understand the technology of the '802 Patent, and even those educational requirements proffered by Dr. Amiji for his idea of a PHOSITA. Moreover, Mr. Haidri has had specific familiarity with the '802 Patent technology since 2018 because of his prior representation of the Plaintiff. In addition, Mr. Haidri is presented by the Plaintiff here as an expert in patent law as well as in the technology taught by the '802 Patent.

---

[27] *In re. Gleave*, 560 F.3d 1331, 1332 (Fed Cir. 2009), citing *Eli Lilly & Co. v. Zenith Goldline Pharms, Inc.,* 471 F.3d 1369, 1373 (Fed. Cir. 2006); *Net Money IN, Inc. v. Verisign, Inc.* 545 F.3d 1359, 1370 (Fed. Cir. 2008); *In re. Bond,* 910 F.2d 831, 832-33 (Fed. Cir. 1990).

However, the purpose of this section of the brief is to argue that Dr. Amiji misinterpreted the statutes and legal standards that deal with unpatentability based upon prior art. As argued *supra*, a claim is anticipated under 35 U.S.C. § 102 if a single prior art reference teaches every limitation of the claim. As discussed above, Dr. Amiji argued that the claims at issue are invalid in view of Wadstrom alone, in view of Wahi '488 alone, and in view of Baker '189 or Baker '476 alone. Here, Dr. Amiji refers to single prior art references, thus invoking the anticipation standard.

In Dr. Amiji's deposition at 54:2-55:21, the following question and answer session ensued:

Q: Do you understand the difference between anticipation and obviousness, then?
A: **Again, in the context of when I'm looking at it as a technical expert.**
Q: So, wouldn't you agree that for a claim to be anticipated, a single prior art reference must encompass every element in that claim?
A: **Yes. That's the standards that you apply for anticipation.**
Q: Wouldn't you also agree that for a claimto be obvious over prior art, in Section 103, a combination of prior art references must be used to encompass every element of the claim?
A: **That's my understanding. and again, for obviousness analysis, the prior art can be combined in order to then come to all the elements of the claim.**
Q: So, the combination must produce all the elements of the claim?
A: **Must provide evidence to a person of skill in the art with reasonable expectation of success.**
Q: And that is a difference between anticipation requiring a single reference that's going to do everything and a combination of references, which in other words, anticipation is all done with

one -- am I correct in terms of your understanding that anticipation requires only once a single references and obviousness requires a combination of references; is that your understanding?

A: **That's generally where -- and that's the analysis that I've done, that for a claim to be invalid, it is anticipated by a single item of prior art.**

Q: Okay. So you would agree that if a single prior art reference does not encompass every element of the claim, that claim cannot be invalid over that single prior art reference alone, am I correct?

A: **Only under the anticipation argument, but it can certainly be invalid based on the obviousness argument.**

This last answer is an incorrect interpretation of the obviousness standard. A claim is neither anticipated nor obvious over a single prior art reference unless every limitation of the claim is taught in that reference.

Finally, it is difficult to ascertain the standards used by Dr. Amiji to allege invalidity of the claims at issue of the '802 Patent. He labels his section with the heading, "Anticipation and Obviousness." (ECF 56-2, pg. 44.) However, he does not say whether the claims are anticipated or obvious. He merely uses the catch-all term, "invalid." Certainly, where he proposes combining the prior art references, he alleges obviousness. However, 35 U.S.C. § 103 requires that obviousness must be determined through the lens of a PHOSITA. In his deposition, Dr. Amiji testified that he considers himself to be a PHOSITA. (Depo. Amiji, 81:22 - 82:8.) However, Dr. Amiji is a person having extraordinary skill in the art. But,

Dr. Amiji is determining obviousness of the claims through his own viewpoint. What is obvious to him is not necessarily obvious to the PHOSITA whose qualifications were already determined by this Court.

Dr. Amiji has already presented his opinions on anticipation and obviousness under 35 U.S.C. §§ 102, 103. He has neither already opined, nor is he necessarily able to opine, on the determination of obviousness of the claims of the '802 Patent at issue through the lens of the PHOSITA who was accepted by this Court.

V. CONCLUSION

Patents are presumed valid. 35 U.S.C. § 282(a). *Structural Rubber Prods. Co. v. Park Rubber Co.,* 749 F.2d. The burden of proof of invalidity rests with the Defendant, who must do so with clear and convincing evidence. *Microsoft v. i4i*, 564 U.S. In an effort to prove invalidity of the '802 Patent claims at issue, the Defendant engaged Dr. Amiji as an expert witness. Dr. Amiji has impressive credentials in pharmaceutical science. He is a registered pharmacist with a PhD, and he is a professor of pharmaceutical sciences and chemical engineering. However, rather than presenting his opinions as a pharmacist or as a chemical engineer, he wrote expert reports that were replete with legal opinions. But, Dr. Amiji is not a lawyer. He is not licensed by the USPTO. He has not been trained in patent

law. And, his opinions show that he does not understand the law and that he misinterpreted the meaning of the statutes and the standards of review stemming therefrom.

Dr. Amiji presented an opinion on the qualifications of a person of ordinary skill in the art (a PHOSITA), which the court rejected. He presented opinions alleging that the claims at issue are invalid under 35 U.S.C. §§ 101, 112, 102, and 103. The arguments presented herein *supra* show that Dr. Amiji does not understand the law. When asked whether a formulation that actually inhibits infection due to inhalation of harmful particles would be useful, he said that it would not. He did not use the correct §101 standard to opine on subject matter eligibility. Dr. Amiji did not do his own research, but instead was asked to opine on claim validity based on prior art patent references provided to him by counsel. He opined that a claim could be obvious over a single prior art reference alone even where that reference did not teach every limitation of the claim. He opined that the claimed invention was obvious to a PHOSITA even though he questioned whether the claimed invention would actually work. Finally, when opining on obviousness (under 35 U.S.C. § 103) and the written description and enablement requirements (under 35 U.S.C. § 112), he did not use the correct qualifications of a PHOSITA that the Court accepted.

Instead he did so through his own lens, because he considers himself to be a PHOSITA.

On page 4 of his report (ECF 56-3), Amirali Haidri wrote:

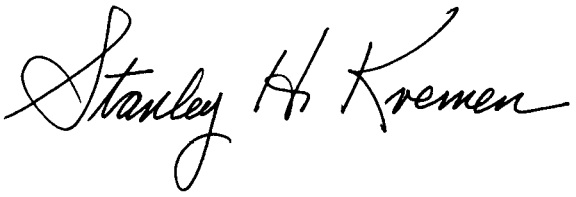
> Obviousness is a legal conclusion. *E.g., Aktiebolaget Karlstads v. United States ITC*, 705 F.2d 1565 (Fed. Cir. 1983). It is a question of law to be determined from the facts. *In re. Geiger,* 815 F.2d 686 (Fed. Cir. 1987); *in re. Blauwe,* 736 F.2d 699 (Fed. Cir. 1984). "Whether an invention would have been obvious in terms of §103 is ultimately a legal judgment, dependent from the factual evidence adduced." *Burlington Indus. Inc. v. Quigg,* 822 F.2d 1581 (Fed. Cir. 1987).

This brief does not argue the validity or invalidity of the '802 Patent. Instead, it argues that any opinion testimony from Dr. Amiji on the subject would be unreliable under Fed. R. Evid. 702 because he is not qualified to provide the opinions thus far expressed by him, and because the basis for his opinions are incorrect. Plaintiff's and Defendant's experts are expected to disagree. Mere disagreement among experts should not itself be a basis for disqualification of one expert *versus* another. However, the basis for expert's opinions must be reliable. Regardless of an expert's credentials, his opinions should not be considered reliable merely because he proffered them. "Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *General Elec. Co. v. Joiner*, 522 U.S. 136, 137 (1997).

For the reasons argued *supra*, Dr. Amiji's testimony regarding invalidity of the '802 Patent should be excluded.

Dated: March 28, 2023

Respectfully Submitted,



Stanley H. Kremen
4 Lenape Lane
East Brunswick, NJ 08816
Telephone: (732) 593-7294
Facsimile: (732) 312-5218
shk@shk-dplc.com
Attorney for Plaintiff

Keith Altman, Esq.
Law Office of Keith Altman
33228 West 12 Mile Road, Suite 375
Farmington Hills, Michigan 48334
Telephone: (987) 987-8929
keithaltman@kaltmanlaw.com
Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

CIVIL ACTION No. 4:21-cv-10312

Hon. F. Kay Behm

CERTIFICATE OF SERVICE

Undersigned hereby states that on March 28, 2023, the attorneys for Plaintiff caused the foregoing document to be served upon all counsel of record, via electronic service.

Stanley H. Kremen
Attorney at Law
4 Lenape Lane
East Brunswick, NJ 08816
Telephone: (732) 593-7294
shk@shk-dplc.com
Attorney for the Plaintiff

Keith Altman
The Law Office of Keith Altman
38228 West 12 Mile Road, Suite 375
Farmington Hills, Michigan 48334
Telephone: (248) 987-8929
keithaltman@kaltmanlaw.com
Attorney for the Plaintiff